Site visit inspection report on compliance with HTA minimum standards
Salisbury NHS Foundation Trust

HTA licensing number 11102

Licensed for the

- **procurement and distribution of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007**

8 October 2015

Summary of inspection findings

The HTA found the Designated Individual (DI), the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

Salisbury NHS Foundation Trust (the establishment) was found to have met all HTA standards.

Particular examples of strengths and good practice are included in the concluding comments section of the report, along with advice and guidance on how to improve systems further.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful

treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity.

'TPA'= Third party agreement, the establishment is licenced for this activity but another establishment (unlicensed) carries out the activity on their behalf

Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
PBSC	**E**		**TPA**		**TPA**	**-**	**-**

Background to the establishment and description of inspection activities undertaken

The establishment undertakes the collection of adult autologous peripheral blood stem cells (PBSC). Procurement of PBSC from paediatric patients takes place at Southampton General Hospital. Young adult patients (19-24 years old) have the option to stay at the establishment or undergo procurement at Southampton General Hospital.

Consultant haematologists are responsible for obtaining consent for procurement and a second consent check is performed by the apheresis team on the day of the procedure. The establishment has one apheresis unit and in the past year conducted sixty-one PBSC procurements. An agreement is in place with a HTA licensed establishment as a contingency for equipment failure and to allow staff to maintain competency. Apheresis kits and reagents are stored in a secure, designated area (see advice item 8).

Procured cells are transferred to another HTA licensed establishment for processing and storage, under the terms of a service level agreement (SLA). Virology testing of donor blood samples is also covered under a SLA with another HTA licensed establishment.

PBSC are no longer returned to the establishment, for autologous transplantation. Since 2014, patients have travelled to Southampton General Hospital for PBSC transfusion. Patient care then continues under the supervision of staff at Salisbury NHS Trust.

A routine inspection of the establishment took place on 8 October 2015. This was the fifth HTA inspection of the establishment that has taken place since the licence application. This is in accordance with the requirements of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 which require all establishments in the human application sector to be inspected with a site visit every two years. The inspection consisted of interviews

with the Designated Individual (DI) and key staff members working under the licence, a review of relevant documentation and visual inspection of the premises.

An audit of patient records was undertaken as part of this inspection. Records for six cases were reviewed from procurement to end use. The audit trail included consent forms for procurement of stem cells and consent forms for processing, testing, storage and subsequent transplant. Records reviewed included: donor virology testing records; stem cell mobilisation records; stem cell harvest record sheets and records of transport of stem cells to the processing establishment, records of delivery of cryopreserved PBSC from the processing laboratory to Southampton General Hospital for transfusion (see advice item 9). The clinical notes were checked to confirm that the unique identifier relating to the harvest was recorded. Full traceability was demonstrated and no anomalies were found.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

The HTA advises the DI to consider the following to further improve practices:

No.	Standard	Advice
1.	GQ1d	SOPs are regularly reviewed and paper copies of the updated documents are placed in the relevant wards. However, no checks are in place to ensure that staff have read the SOPs. The DI is advised to implement a procedure to ensure that a log sheet is signed by the relevant staff every time a change is introduced to an SOP.
2.	GQ1e	On the day of procurement, a blood sample is sent to another establishment to determine $CD34^+$ cell levels. As there is some delay in receiving these results, the establishment relies on the white blood cell count to determine whether PBSC procurement will take place. This may sometimes result in the patient undergoing an unnecessary procedure if the $CD34^+$ count is subsequently found to be below an acceptable level. The DI is advised to hold discussions with the testing establishment to determine whether $CD34^+$ results might be obtained sooner or consider delaying PBSC procurement by a few hours. The DI is also advised to maintain a traceability record of the dispatch and receipt details for the blood samples and a record of the $CD34^+$ levels.
3.	GQ1g	PBSC are packaged in sealed transport containers and sent to a licensed establishment for processing. Traceability details are recorded on form 2M by the establishment and the receiving laboratory. A number of anomalies were found: • Both establishments do not generally enter a temperature reading but descriptors such as “cool” or “normal.” If a temperature reading is entered by the processing establishment, it is unclear what this temperature measurement refers to, for e.g. the temperature of the

		outer box or the PBSC. • On a number of forms there were discrepancies between the time the PBSC unit was received and the time the temperature was recorded. • Receipt details were missing in some forms. The DI is advised to: • Review the agreement in place with the processing laboratory to ensure that critical transport conditions required to maintain the properties of the stem cells are defined and documented. • To check records for completeness.
4.	GQ1r	Transfusion of PBSC takes place at Southampton General Hospital. Patients then return to the establishment to continue their treatment. The agreement between the establishment and Southampton General Hospital does not make any reference to the management of a serious adverse event or reaction (SAEARS) and how the establishment will be informed.
5.	GQ2b	Internal audits are carried out on a regular basis by a member of staff closely involved with all the activities. The audit reports are not signed or dated. The DI is advised to nominate someone independent to carry out the internal audits and to ensure records are signed and dated for completeness.
6.	GQ4b & GQ4i	Within the patient notes there is a folder containing all the paperwork associated with the PBSC procurement, processing and use. The SOP states that the form 2M detailing the transfer of the PBSC to another establishment should be placed in this folder. Only one out of the six files examined contained this form. The SOP also states that a sticker requesting retention of the folder for 30 years should be placed on the file. None of the files had this sticker. Other forms reviewed had errors covered in correction fluid or crossed out but not initialled or dated. The DI is advised to review records for completeness.
7.	GQ7c	The DI is advised to provide SAEARS refresher training for all staff involved in the licensable activities.
8.	PFE3a	The consumables for the apheresis machine are stored in a secure room and the temperature is monitored once daily during the working week but not on a regular basis over the weekend or during holiday periods. The DI is advised to extend the daily temperature checks to included weekends and holidays.
9.	PFE4h	The validation of the transport boxes is out of date and the boxes currently being used are no longer available. The DI is in discussions with another establishment for advice on what transport boxes to purchase and validate. The DI is advised to complete the validation as soon as possible and provide the HTA with a copy of the validation report.
10.	PF5b	The SOP and service contract for the apheresis machine states that two service visits per year take place. The service record reviewed was dated October 2014. The DI is advised to ensure that the apheresis machine is serviced according to the SOP.
11.	D2a	The disposal policy lists the names of staff permitted to dispose of PBSCs. The DI is advised to review the disposal policy and remove the name of staff that no longer work at the establishment.

Concluding comments

The HTA saw various examples of good practice during the inspection. Staff working under the licence are a small, well integrated and committed team. Staff receive on-going training at the establishment and training on the apheresis machine is particularly thorough. In addition to the internal training programme staff are able to gain further hands-on experience at another licensed establishment to ensure that levels of competency are maintained despite the relatively low level of activity There is good control over SOPs and a register is maintained detailing the location and versions of the documents. A regular review of the stored PBSC is conducted and discussions are held with patients before disposal. The establishment has an effective succession plan in place to deal with the imminent retirement of a senior member of the team.

The HTA has assessed the establishment as suitable to be licensed for the activities specified. To improve practice, the DI has been given advice and guidance on a range of issues covering governance and quality standards as well as premises, facilities and equipment arrangements.

Report sent to DI for factual accuracy: 29th October 2015

Report returned from DI: 19th November 2015

Final report issued: 19th November 2015

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below. Individual standards which are not applicable to this establishment have been excluded.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) and the HTA's Codes of Practice
c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 003/2010 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.
d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.

b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the European directives on medical devices and in vitro diagnostic medical devices.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 003/2010.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.

d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.
i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 003/2010, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 003/2010.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.
j) Records are kept of products and material coming into contact with the tissues and / or cells.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 003/2010.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan to ensure records of traceability are maintained for 10 or 30 years as required.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 003/2010.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 003/2010.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.
c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances

the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24 hour basis.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 003/2010.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.

i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.

Appendix 2: Classification of the level of shortfall (HA)

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

   Or

   A number of 'major' shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered 'critical'.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall.

   A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

   or

   A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

   or

   A shortfall which indicates a major deviation from the **Human Tissue (Quality and Safety for Human Application) Regulations 2007** or the **HTA Directions**;

   or

   A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

   or

   A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major

shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.